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C O N F I D E N T I A L SECTION 01 OF 04 WELLINGTON 001037

SIPDIS

DEPARTMENT FOR EAP/ANP-TRAMSEY AND EB/TPP/BTA/ANA-RARMSTRONG
STATE PASS TO USTR FOR BWEISEL AND DKATZ
COMMERCE FOR 4530/ITA/MAC/AP/OSAO/GPAINE

E.O. 12958: DECL: 12/14/2014
TAGS: ETRD ECON KIPR NZ
SUBJECT: NEW ZEALAND'S PHARMACEUTICAL MARKET: NO QUICK FIX

REF: A. WELLINGTON 900

¶B. AUCKLAND 302
¶C. AUCKLAND 118

Classified by: DCM David R. Burnett. Reasons: 1.4 (b) and (d).

¶1. (SBU) Summary: After trying in vain for years to persuade the New Zealand government to change its restrictive pricing policies on pharmaceuticals, the drug industry is taking another tack: reaching out to patient groups with information designed to bolster their demands for cutting-edge drugs not already covered by government subsidy. Several U.S. drug companies also hold out hope that a New Zealand-U.S. free-trade agreement could be a lever for improving their access to New Zealand's pharmaceutical market.

¶2. (C) The government contends it already is increasing drug availability by boosting the budget for pharmaceutical purchases over the next three years. In actuality, its spending on drugs in real terms is declining. U.S. pharmaceutical companies continue to struggle in what they view as one of the most restricted free-world markets. They are cutting local staff, and they are slashing investment in New Zealand-based research and development. Attempting to make inroads against a government mindset that is hostile to the drug industry, post is working with the industry to identify speakers and engage in other public diplomacy efforts that could help educate New Zealanders on the benefits of gaining access to a wider range of effective pharmaceuticals. End summary.

Limited prices, limited access
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¶3. (U) Spending in New Zealand on government-subsidized pharmaceuticals has risen by less than three percent per year on average during the last decade, compared to 14 percent per year in Australia. Only six new drugs a year were approved on average over the last three years for reimbursement in New Zealand, compared to about 30 drugs in Australia. The New Zealand government nevertheless asserts that it now is increasing the budget for pharmaceuticals sufficiently to subsidize more new medicines.

¶4. (U) In fact, the pharmaceutical budget rose this fiscal year (ending June 30) by 4.4 percent, to NZ $541 million (US $380 million), with planned increases in the following two years of .5 percent and 1.9 percent. The smaller increases in the 2006-2007 and 2007-2008 budget years were based on the expectation that a number of expensive drugs will go off patent, according to Stuart Bruce, manager of communications and external relations for the Pharmaceutical Management Agency (Pharmac), a stand-alone Crown entity.

¶5. (U) Exempt from New Zealand's competition law, Pharmac acts as a single buyer, or monopsony, that decides which medicines will be subsidized by the government and how much reimbursement will be paid for each pharmaceutical. In some cases, the supplier is not allowed to set a drug price higher than the subsidy as determined by Pharmac. The agency also puts a cap on the amount of a drug to be purchased at a certain price. Its decisions effectively allocate about 73 percent of New Zealand's spending on prescription drugs. Pharmac does not directly handle funding for the government's drug subsidy. Those funds are dispersed by the national health care systems' 21 district health boards to the pharmaceutical suppliers after a prescribed drug is dispensed to the consumer.

¶6. (SBU) Bruce noted that Pharmac always under-spends its budget because government policy prohibits exceeding it. That means that actual public spending on pharmaceuticals is likely to remain relatively flat or even decline in real terms over the next three years. Further explaining why Pharmac spends less than planned, Bruce said that some patients do not pick up their prescriptions because of co-payment delays. Spending projections also are based on the assumption that patients will consume their entire prescription. Since pharmacists receive a fee each time they dispense a medication, they usually break a prescription into installments, and some patients do not purchase an entire

prescription.
¶7. (C) Pharmac designated 15 new products for reimbursement the past fiscal year, up from three new drugs in 2002-2003. U.S. pharmaceutical firms we talked to, however, point out that only one of those new medicines is freely available. Access to the other medicines is available only after doctors make special application or when patients meet specific criteria. For example, only specialists can prescribe a new treatment for diabetes. The drug's manufacturer believes 2,000 to 3,000 of the more than 100,000 diabetics in New Zealand could benefit from the medicine. But with just 50 specialists nationwide, most patients are under the care of general practitioners, and obtaining the drug is difficult. Another company reported that six out of 10 applications by doctors for reimbursement for its schizophrenia drug are rejected.

¶8. (C) The industry also criticizes Pharmac for a lack of transparency in its funding decisions. One U.S. company spent more than three years negotiating with Pharmac to gain public funding for a schizophrenia treatment. Without explanation (none is required), Pharmac broke off those discussions this year.

¶9. (U) The New Zealand industry group Researched Medicines Industry (RMI) said in a statement that Pharmac is using "smoke and mirrors" to portray itself as widening New Zealanders' access to pharmaceuticals. Since leading-edge medicines generally are not subsidized, they are available only to those who can pay the full cost, RMI said.

¶10. (SBU) Publicly, Pharmac contends that it delivers the best health-care outcomes possible within the funding available, citing the fact that the volume of subsidized pharmaceuticals has increased while prices in general have declined. Pharmac highlights the savings it reaps -- NZ $25 million (US $17.5 million) the past fiscal year -- that would have been spent on the drug subsidy without its intervention to lower prices. Privately, Wayne McNee, Pharmac's chief executive officer, acknowledged that the principal obstacle to funding more medicines is the government's reluctance to increase the pharmaceutical budget. On that, both he and the industry agree.

IPR and advertising under threat
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¶11. (U) U.S. pharmaceutical companies consider New Zealand's patent protection to be inadequate. Pharmac controls pharmaceutical prices partly through "reference pricing" -- determining the level of subsidy based on the lowest-priced product in a therapeutic subgroup. The subgroup includes medicines that are similarly effective in treating the same or similar conditions. This policy often pits patented products against lower-priced generics and does not reward innovation. Pharmac's general practice is to designate for subsidy only one drug per therapeutic class.

¶12. (U) The New Zealand government also has refused to extend the effective patent life of drugs, which now stands at seven years on average (ref A). One U.S. company views the issue as irrelevant, since Pharmac's reference pricing undermines its patents' commercial value anyway. Most companies see the government's position on effective patent life as further evidence of its disregard for the pharmaceutical industry. Further eroding their patents' worth is the so-called springboarding provision in New Zealand's patent law, which allows generic competitors to start the process of seeking market approval while a proprietary drug is still under patent.

¶13. (C) In addition, U.S. pharmaceutical companies continue to worry that the government will ban direct-to-consumer advertising, one of the industry's few pathways around Pharmac's controls (ref C). Several companies, especially those marketing so-called lifestyle drugs for such conditions as hair loss and erectile dysfunction, have built sales through advertising. Unsubsidized drugs accounted for 30 percent of sales for Merck Sharp & Dohme, 25 percent for Pfizer, 20 to 25 percent for Pfizer, 20 percent for Johnson & Johnson, 15 percent for Eli Lilly and less than 6 percent for GlaxoSmithKline this year in New Zealand. Health Minister Annette King and Pharmac oppose direct-to-consumer advertising (DTCA) partly because they believe it tends to increase expenditures on pharmaceuticals. DTCA also pressures Pharmac to explain why it does not fund certain advertised drugs. Companies are wary of the New Zealand government using a joint regulatory agency it is establishing with Australia as a vehicle for banning DTCA, which is not allowed in Australia. However, the Australian High Commission told post that such a decision is for the New Zealand government alone to make.

A big hit on industry
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¶14. (U) From Pharmac's pricing policies to the government's positions on intellectual property and direct-to-consumer

advertising, U.S. pharmaceutical companies consider New Zealand to be hostile ground. Unable to meet their sales and profit targets, they say it is becoming increasingly difficult to persuade their home offices to keep investments or even a presence in the country.

¶15. (C) As a result, almost all U.S. companies in New Zealand have scaled back their staffs and their research-and-development investments since Pharmac was formed in 1993. During the past year, Eli Lilly cut 20 percent of its staff to 27 people, from a peak of 70 employees in the mid-1990s. GlaxoSmithKline has reduced its staff by 65 percent, down to about 50 people. Pfizer downsized its pharmaceutical division by 15 percent, to 60 people. Johnson & Johnson two years ago cut its staff by 10 percent, and Jan Trotman, its general manager in New Zealand, said that if conditions do not improve in 2005, the company could leave the country in three to five years. (Some staff cuts are due to the shifting of regulatory oversight from New Zealand to Australia with the scheduled launch of the trans-Tasman agency in July 2005.) The exception is Merck, where employment has remained stable and sales have increased, partly because of its higher sales of vaccines.

¶16. (C) Because of the difficult environment, all the companies have reduced -- and, in some cases, ceased -- investment in research and development in New Zealand (ref B). Eli Lilly is completing two clinical trials, but otherwise has transferred all its research and development. Ten years ago, every U.S. drug company in New Zealand employed a medical director. Now, only Merck has one. Ironically, New Zealand presents a small but optimal environment for clinical trials of pharmaceuticals because of its population's lack of exposure to newer medicines. Minister King had threatened to end clinical trials unless patients participating in a trial had free, lifetime access to the medicine once the trial ended. Other cabinet ministers told her to stop making that threat.

¶17. (SBU) Nearly every company said it was holding out some of its newer medicines from New Zealand because of the expectation that prices and sales volumes would be too low. For the New Zealand consumer, the result is less access to modern medicines.

Times they are a-changin'?
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¶18. (SBU) Pharmaceutical companies see ideological opposition to their industry in comments by Prime Minister Clark, Health Minister King and other cabinet members. One pharmaceutical executive recalled how, upon simply introducing himself at a public forum, the Prime Minister said the drug industry needed to be "stopped" from making excessive profits. (The industry may be paying a price for its unsuccessful effort in 1990 to unseat Clark, who at the time was health minister.) Health Minister King has publicly equated the pharmaceutical industry with the tobacco industry. When several companies warned her that her government's policies would force the industry out of New Zealand, she responded that she was not concerned because New Zealand could always shop overseas for its drugs.

¶19. (SBU) Amid such perceived hostility, there have been subtle changes. In the past couple years, RMI and Pharmac have worked to maintain dialogue, although RMI in recent months under a new chairman -- a general practitioner -- has more aggressively promoted the industry's views in the media. While drug companies remain unhappy with Pharmac's practices, they see capped government funding, rather than Pharmac itself, as their primary problem. Several companies noted an emerging public debate over access to medicines, a discussion that was nonexistent even a couple years ago. Public attitudes are changing slowly. As Alister Brown, Merck New Zealand's chief executive, noted, consumers five years ago assumed that if Pharmac did not fund a drug, it was not worth having. An increasing number of consumers are now willing to pay for non-subsidized drugs.

¶20. (C) Finding that its direct pressure failed to alter the government mindset, the industry is now firing up pressure from below. For the last six months, RMI has been working with patient groups to make them aware of cutting-edge pharmaceuticals that are not being subsidized in New Zealand. Lesley Clarke, RMI's chief executive officer, hopes this effort will result in increased pressure on the government to hike funding for drugs. Although Clarke said it would be too early to see results of RMI's efforts, New Zealand newspapers in recent months have reported complaints by patient groups over the lack of funding for drugs to treat breast cancer, Alzheimer's disease, and growth hormone problems.

¶21. (SBU) New Zealand's doctors would appear to be likely cheerleaders for greater access to pharmaceuticals. However, industry market research shows that fewer than 20 percent of New Zealand's doctors would tell their patients of non-funded alternatives to subsidized medications. The drug companies

contend that doctors are reluctant to publicly call for change.

¶22. (C) A possible U.S.-New Zealand free-trade agreement (FTA) offers one last avenue for changing government policies that limit access to pharmaceuticals, several U.S. companies said. Meanwhile, Geoff Dangerfield, chief executive of the New Zealand Ministry of Economic Development, told a U.S. drug company that his government terminated its study of patent term extension for pharmaceuticals to keep the issue as a bargaining chip in the event of FTA negotiations. If FTA talks go forward, most of the drug companies will be looking to the U.S. government to win serious concessions from New Zealand on pharmaceutical issues. Pfizer, which withdrew from RMI early this year, will oppose free-trade negotiations until the New Zealand government alters some of its policies, especially its patent law and reference pricing.

Post's strategy
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¶23. (SBU) The challenge is compounded by New Zealand's escalating health-care costs and an aging population. Overall health-care spending has risen faster than any government budget category since 1994 and now comprises about 20 percent of the government budget. In the meantime, the government's effort to reduce the cost of seeing a doctor has led to more patient visits, more prescriptions, and more purchased pharmaceuticals. As a result, Bruce of Pharmac said his agency would face more pressure to ration its budget or seek a larger portion of the already stressed health budget.

¶24. (C) To complement the industry's efforts, post will work with companies to identify U.S. speakers to be brought to New Zealand and possible International Visitor Program participants, with the goal of educating New Zealand's health practitioners, policymakers and consumers on pharmaceuticals' role in health care. These programs will emphasize the advantages of expanded access to medicines and treatment options and the link between pharmaceutical research and development and the biotechnology industry, which the New Zealand government prominently supports as a means to economic growth. By keeping drug expenses artificially low, the New Zealand government is denying consumers access to many modern medicines and failing to bear an equitable portion of the cost of developing drugs. Over the long term, post hopes its efforts will help New Zealand strike a balance between providing affordable medicines and supporting an industry that creates cures for disease.
Swindells